



Naval Health Research Center Update

FOURTH QUARTER

WINTER 2011

Research Integrity Corner

**"What are
the
main
ethical
principles
that
govern
research
with
human
subjects?"**

HOW
WOULD
YOU
RESPOND?

- Page 18

Respiratory Disease Diagnostics

Story—Page 2



Readiness Through Research and Development

Over 50 Years of Excellence

1959 ~ 2011

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Respiratory Disease Diagnostics

In 1996, Naval Health Research Center initiated Febrile Respiratory Illness (FRI) surveillance at military recruit centers across the United States. Since then, the Department of Respiratory Diseases Research (DRDR) has served as the premier Department of Defense (DoD) laboratory for the surveillance, diagnosis, and characterization of respiratory infections of operational importance.

In 2007, DRDR expanded its FRI surveillance to a local military-dependent population. In addition to providing valuable epidemiologic data and augmenting NHRC's specimen archive, the study established an infrastructure ideally suited for the evaluation of novel respiratory disease diagnostic tests.



LG Eric Schoomaker Army Surgeon General and CAPT Kerry Thompson visited the Great Lakes site.

Four influenza diagnostic platforms have been assessed in the dependent population over the last 4 years.

1. The first, conducted during the 2007–2008 influenza season, evaluated a seasonal influenza (types A and B) and avian influenza (A/H5N1) assay based on proprietary technology from the Arbor Vita Corporation (Fremont, CA). That study, in collaboration with Naval Medical Research Unit 3 in Cairo, Egypt, led to subsequent Food and Drug Administration (FDA) licensure of AVantage, the only point-of-care avian influenza assay on the U.S. market.
2. Two other rapid point-of-care influenza diagnostics were evaluated during the 2008–2009 influenza season. During the testing of a rapid platform from Meso Scale Discovery, a specimen from the first case of pandemic 2009 H1N1 influenza was collected and subsequently identified.
3. During the 2010–2011 season, the Joint Biological Agent Identification and Diagnostic System (JBAIDS), a rapid portable ruggedized laboratory system for the detection of multiple biological warfare agents, was evaluated in cooperation with Idaho Technology, Inc. The JBAIDS device will soon be deployed for use by the DoD.
4. Finally, DRDR partnered in 2009–2010 with Rapid Pathogen Screening (RPS), Inc. (Sarasota, FL) to evaluate the RPS Adeno Detector, a point-of-care test strip designed to identify adenovirus from throat swabs in military recruits presenting with FRI. Test results were compared with microbiological and molecular laboratory results and were found insufficiently concordant to merit FDA submission. DRDR intends to evaluate RPS's new influenza A test device (similar in design to the Adeno Detector) in 400 military dependents from the above surveillance population during the upcoming season.

NHRC Researcher Receives Top Scientist Award

Assistant Secretary of the Navy for Research, Development and Acquisition Sean Stackley recognized the 2010 Dr. Delores M. Etter Top Scientists and Engineers of the Year award winners during a ceremony held on July 15 at the Pentagon.

The distinguished group of individuals were honored for their achievements, professionalism and technical excellence.

"These naval scientists and engineers are visionary thinkers and innovative problem solvers," said Chief of Naval Research Rear Admiral Nevin Carr, keynote speaker for the event. "Today, we honor their achievements as shining examples of what bright, hard-working people can do to deliver significant advanced capabilities for ships, aircraft, submarines and expeditionary forces."

Representing the Bureau of Medicine and Surgery, Naval Health Research Center (NHRC), Commander Patrick Blair received the Assistant Secretary of the Navy Research, Development and Acquisition's 2010 Dr. Delores M. Etter, Top Scientists and Engineers of the Year Award for his contribution in the early recognition and response to the 2009-2010 A/H1N1 (swine) influenza pandemic.

CDR Blair and his colleagues reported the first two cases of H1N1 in April 2009 as part of a collaborative effort with the Centers for Disease Control and Prevention (CDC) to conduct surveillance along the border



From left: Sean J. Stackley, Assistant Secretary of the Navy (Research, Development and Acquisition); Cmdr. Patrick J. Blair, Naval Health Research Center; Dr. Delores M. Etter, former Assistant Secretary of the Navy (Research, Development and Acquisition).

between the United States and Mexico. Influenza sequence information and isolates were shared with the CDC, and the NHRC-isolated virus ultimately became the seed strain in the 2009-2010 H1N1 vaccine. NHRC was awarded the CDC Reference Laboratory of the Year Award for this work.

"I am pleased to share in the 2010 Delores M. Etter Science Award," said Blair. "I am well cognizant that this honor is a reflection of the diligence and hard work the NHRC laboratory and administrative team bring each day to our mission to achieve force protection."

NHRC is considered a key surveillance and diagnostics center for San Diego's fleet concentration area and for the

entire southwestern United States. The laboratory conducts surveillance of respiratory pathogens for all Department of Defense training activities, Pacific Rim Navy and Marine Corps stations, and over 20 large-deck U.S. Navy ships.

Their work contributes directly to force health protection by defining critical respiratory pathogen threats and directing appropriate intervention strategies. The laboratory's work in diagnosis, training, outbreak response and clinical trial development for novel therapeutics has brought great credit to the Navy and provides a clear public health benefit to service members and their families around the world.



Toolkit designed to reduce the stigma associated with seeking help



Suzanne Hurtado

Photo courtesy of NHRC Public Affairs

The Behavioral Sciences and Epidemiology Department at Naval Health Research Center (NHRC) focuses on the studies of psychological health and the effects of combat exposure on Marines and sailors.

Part of that mission includes developing and evaluating materials to mitigate stress and improve the health of returning service members.

Researchers are developing a toolkit to reduce the stigma associated with seeking help for stress concerns among Marines. the toolkit is being designed to help senior enlisted leaders create a climate where Marines can

comfortably seek help for stress concerns as well as provide practical materials to enhance communication and reduce barriers to seeking care for stress injuries and other behavioral health issues.

Ultimately, creating an environment that encourages Marines to seek behavioral health assistance that protects the readiness and effectiveness of

not only the individual Marine, but of the entire unit.

One of the objectives of the toolkit is to address negative attitudes toward mental health treatment. To meet this objective, project investigators Ms. Suzanne Hurtado, Ms. Cynthia Simon-Arndt and Ms. Jenny Crain interviewed mental health professionals (MHPs) at the Naval Medical Center San Diego (NMCS) for a video to demystify mental health treatment.

Three MHPs with a range of experience providing care to Marines, including in-theater, at 1st Marine Division, and at NMCS, participated in the interviews.

The MHPs explained common treatments for stress

injuries and illnesses, as well as the benefits of early intervention. They also discussed topics important to service members such as confidentiality, medications and deployability, and support when a service member is reintegrated into the unit after treatment.

The video represents collaboration between the research and treatment communities to address barriers to care and enhance the accessibility of treatment to service members with mental health concerns.

It is designed for use by senior enlisted leaders to educate their Marines and dispel myths about the nature of mental health treatment.

When completed, the video and the toolkit, of which it is a part, will provide another means of battling stigma and preventing the potentially harmful consequences of untreated stress injuries on individual Marines and Marine Corps mission readiness.



Antisocial Behavior trends studied

A unique finding of this study was the link between deployment-related stressors and antisocial behavior.

This is an important finding because deployment stressors (e.g. lack of time off and boredom) are potentially modifiable by the military.

While mental health concerns among combat veterans have been extensively studied, awareness of combat-related behavioral health problems is also growing. Consequently, researchers in the Behavioral Sciences and Epidemiology Department at Naval Health Research Center (NHRC) have increasingly focused on behavioral trends among service members.

Some of NHRC's recent work was summarized by Dr. Stephanie Kewley and Dr. Jerry Larson during an invited presentation entitled "*Correlates of Antisocial Behavior Among Marines*" at Psychiatry Grand Rounds, Naval Medical Center San Diego.

Dr. Kewley presented a recent study that she conducted, along with

colleagues from NHRC and Headquarters Marine Corps. This study examined factors linked with self-reported antisocial behavior in a large sample of Marine service members.

A total of 1,543 Marines served as study participants; all participants had deployed to combat zones in support of conflicts in Iraq and Afghanistan.

The researchers identified five factors that had significant associations with antisocial behavior:

1. post-traumatic stress disorder (PTSD) symptoms
2. deployment-related stressors
3. combat exposure
4. younger age and
5. being divorced.

A unique finding of this study was the link between deployment-related stressors and antisocial behavior.

This is an important finding because deployment stressors, including factors such as:

- difficulty in communicating with home
- lack of time off
- boredom or monotony and
- problems with supervisors or chain of command

are potentially modifiable by the military.



Dr. Stephanie Kewley and
Dr. Jerry Larson

Dr. Larson shared preliminary findings from a study examining Marines separating from active duty and transitioning back to civilian life.

Among the new Marine Corps veterans who were surveyed for the project, problems with irritability and temper were somewhat common, and were associated with difficulty readjusting to civilian life along with many problematic behaviors such as substance abuse.

The presentation explored conceptual differences between temperamental behaviors (yelling, slamming of doors) and aggressive behavior (threats or perpetration of violence), and described associations between various aspects of anger-expression and mental health.



Command Highlights and Updates

NHRC awarded 2 World Class Modeling proposals

NHRC was awarded two separate OPNAV Assessment Division, Office of the Chief of Naval Operations (N81) World Class Modeling efforts for FY12. The proposals were developed by Mr. Vern Wing with Mr. Johnny Brock and Mr. Jonathan Davis of Teledyne Brown Engineering, Inc.

- The first effort is a modest endeavor to model patient flow through medical treatment facilities and then to compare that model to the Army's government-off-the-shelf (GOTS) products titled, "Global Requirements Estimator for Wartime Medical Support (GREWMS)," and, "Patient Flow Model (PFM)," to evaluate applicability to Navy medical planning needs.
- The second effort will result in the instantiation of Naval Level 3 medical capabilities in the Tactical Medical Logistics Planning Tool (TML+). This project will result in increased TML+ utility by providing the means to emulate the naval theater hospitalization level of care in the simulation tool. OCT 2011.

NHRC awarded Marine Corps Casualty Care Study

NHRC was awarded the Enhanced Marine Air Ground Task Force (MAGTF) Casualty Care Study by the Marine Corps Warfighting Laboratory (MCWL). The proposal to provide this support to the Warfighting Lab was a joint effort between Mr. Martin Hill and Mr. Vern Wing. This study will examine medical support in a variety of new force employment scenarios in an effort to determine optimal personnel utilization and patient care in distributed operations. OCT 2011.

NHRC awarded ONR grant to evaluate post-deployment sleep disruption

Dr. Marc Taylor and Dr. Gerald Larson were awarded a two-year \$350K research grant from the Office of Naval Research (ONR) Code 30 Human Performance Training and Education (HPT&E) program to evaluate post-deployment sleep disruption in Navy SEAL operators. SEPT 2011

CAPT H.R. Bohman, MC, USN retires

CAPT H. R. Bohman, MC, USN retired from naval service 30 Sept. A well-known trauma surgeon with scores of deployments with the Marine Corps, including multiple deployments to Iraq and Afghanistan, CAPT Bohman has worked with NHRC for the past two decades. He was a major contributor to work done by the NHRC Medical Modeling, Simulation & Mission Support Department including the early development of Estimating Supplies Program (ESP), Tactical Medical Logistics Planning Tool (TML+), and the Combat Trauma Registry Expeditionary Medical Encounter Database (CTR EMED), and he was a strong proponent of our military medical modeling and simulation work. On the occasion of his retirement, Mike Galarneau presented CAPT Bohman with a letter of appreciation from NHRC signed by CAPT Gregory C. Utz, M.D. SEPT 2011

Clinical Investigations Directorate Director tours NHRC

Dr John D. ("J.D.") Malone, the new Director of the Clinical Investigations Directorate for Navy Medicine West and Naval Medical Center San Diego (NMCS), and three members of his staff visited NHRC. CAPT Greg Utz, CAPT Doug Forcino, Dr. Karl Van Orden, and Department Heads provided briefings. Tours were taken of the Operational Infectious Diseases Laboratories and Human Performance Laboratory. Dr Malone and his staffs plan on becoming integral members of the R&D-CIP and GME Integration Consortium, established by NHRC and NMCS during the last year. SEPT 2011



Role of Vitamin D in chronic disease prevention

New research has found the many emerging benefits of vitamin D for human health at all ages, including those of active-duty military service members and their dependents. Recent discoveries illustrating the wide range of health benefits of vitamin D in the prevention of chronic diseases include:

Reduction in risk of type 1 diabetes

A study of the association between solar ultraviolet B (UVB) irradiance and type 1 diabetes was conducted by the Naval Health Research Center (NHRC) and University of California, San Diego (UCSD) coauthors in 2008. The results indicated that incidence rates increased at higher latitudes in association with lower UVB irradiance. The incidence rate of type 1 diabetes decreased in areas closer to the equator, where solar UVB intensity is highest in support of the data that vitamin D helps reduce the risk of type 1 diabetes.

Prevention of multiple sclerosis

A nested case-control study in the active-duty Department of Defense (DoD) population was performed by Munger and colleagues of Harvard University. They found that a 20 ng/ml upward increment in serum 25(OH)D was associated with a 40% risk reduction of multiple sclerosis (MS). Another study, by Soilu-Hänninen and colleagues, found that MS patients who relapsed had lower serum 25-hydroxyvitamin D concentrations than those in remission. In a study by Simpson and colleagues, each upward increment of 2 ng/ml of 25-hydroxyvitamin D was associated with reduction in risk of relapse by 12%.

Prevention of intestinal cancer

In a paper published in the *International Journal of Epidemiology*, Dr. Frank Garland and Dr. Cedric Garland theorized that vitamin D and calcium use decreased the risk of colon cancer. Colon cancer mortality rates were compared using maps of solar radiation in the United States. This was one of the first findings of a benefit of vitamin D on risk of cancer.

An 8-year prospective study was then conducted by Drs. Frank and Cedric Garland and colleagues. Blood samples were collected at Johns Hopkins University from 25,620 volunteers and frozen for 8 years.

According to their nested case-control study, colon cancer risk was about 75% higher in people with serum 25(OH)D concentrations below 20 ng/ml compared with those with a concentration of 27–41 ng/ml.

A meta-analysis from NHRC and UCSD reported on five studies of serum 25(OH)D. Odds ratios were 1.00, 0.82, 0.66, 0.59, and 0.46 from the lowest to highest quintile of 25(OH)D compared to risk of colorectal cancer, respectively. The results of this analysis were that intake of 1,000–2,000 IU of vitamin D₃ per day would minimize the risk of colon cancer.

Reduction in incidence of cancer in women

Joan Lappe and colleagues at Creighton University reported the results of a 4-year population-based, double-blind, randomized placebo-controlled trial on the effects of vitamin D

NHRC Staff Awards

The NHRC Staff Awards Ceremony was held on 28 July 2011. CAPT Greg Utz presented the awards to the following recipients:

Navy and Marine Corps Commendation Medal

Major Nisara Granado, Biomedical Science Corps, United States Air Force received the Navy and Marine Corps Commendation Medal award by the Secretary of the Navy for her meritorious service as a member of a source selection evaluation board, NHRC. Major Granado evaluated proposals for a \$490 million multiple performer Omnibus Research Services Contract that will benefit Navy Medicine for years to come.

Navy and Marine Corps Commendation Medal

The Navy and Marine Corps Commendation Medal (Gold Star in Lieu of the Fourth Award) was awarded to **Commander Deborah J. White**,



CDR Deborah White
receives her award
from CAPT Greg Utz

Medical Service Corps, United States Navy, for her meritorious service as a member of a source selection evaluation board, NHRC. CDR White designed, coordinated and brought completion to a complex and comprehensive source selection and evaluation process for a \$490 million multiple performer,

Omnibus Research Services Contract. She created the framework for the evaluation of this omnibus contract and contributed as an evaluator of the management factors of many proposals in both large and small business lots. CDR White's initiative, perseverance and total dedication to duty reflected great credit upon her and were in keeping with the highest traditions of the United States Naval Service.

Special Achievement Award

A Special Achievement Award was presented to **Dr. Edward Gorham** for his outstanding contributions as Chairman, Source Selection Evaluation Board, Naval Health Research Center.

Dr. Gorham demonstrated exceptional leadership and integrity in administering a \$490 million multiple award OMNIBUS research services contract evaluation process, a critical procurement mechanism to support future Department of Defense (DoD), Health Affairs and Bureau of Medicine and Surgery medical research and development (R&D) requirements.

Dr. Gorham consulted with key U.S. Army acquisition professionals, procurement attorneys, and technical experts to develop a performance-based acquisition evaluation strategy which included establishing a baseline assessment of technical evaluation factors to ensure a comprehensive, fair and equitable analysis of large and small business proposals.

He implemented procedures to minimize the selection complexities and inspired his team to critically examine all management capability requirements, ensuring only the best value proposals were recommended to the source selection authority for consideration of contract award and all required documentation for source selection decision remained consistent with statutory principles and resilient to potential protests.

Dr. Gorham's exceptional dedication and unswerving devotion will have a major impact on contractual support of DoD Medical R&D programs for years to come.



NHRC Publications

Andrews, JA; Neises, KD. (2011 NOV) **Cells, biomarkers, and post-traumatic stress disorder: evidence for peripheral involvement in a central disease.** *J. Neurochem.* (2012) 120, 26–36.

Conway, TL.; Hammer, PS.; Galarneau, MR.; Larson, GE.; Edwards, NK.; Schmied, EA.; Ly, HL.; Schmitz, KJ.; Webb-Murphy, Jennifer A.; Boucher, Wayne C.; Johnson, Douglas C.; Ghaed, Shiva G. (2011 NOV) **Theater Mental Health Encounter Data (TMHED): Overview of Study Design and Methods.** *Military Medicine*, 176(11) 1243-1252(10).

Myers CA; Kasper MR; Yasuda CY; Savuth C; Spiro DJ; Halpin R; Faix DJ; Coon R; Putnam SD; Wierzba TF; Blair PJ. (2011 NOV). **Dual Infection of Novel Influenza Viruses A/H1N1 and A/H3N2 in a Cluster of Cambodian Patients.** *Am J Trop Med Hyg.* 85(5):961-3.

Thomsen, CJ; Stander, VA; McWhorter, SK; Mandy M; Rabenhorst MM; Milner, JS. (2011 OCT). **Effects of combat deployment on risky and self-destructive behavior among active duty military personnel.** *Journal of Psychiatric Research*, 45(10):1321-1331.

Macara, C; Aralis, H; Macgregor, A; Rauh, M; Han, P; Galarneau, M. (2011 OCT). **Cigarette smoking, body mass index, and physical fitness changes among male navy personnel.** *Nicotine & Tobacco Research: Official Journal Of The Society For Research On Nicotine And Tobacco*, 13(10):965-971.

Rau, TJ; Merrill, LL; McWhorter, SK; Stander, VA; Thomsen, CJ; Dyslin, CW; Crouch, JL. Rabenhorst, MM; Milner, JS. (2011 OCT). **Evaluation of a Sexual Assault Education/Prevention Program for Female US Navy Personnel** *MILITARY MEDICINE*, 176(10):1178-1183(6).

Broderick MP; Hansen CJ; Russell KL; Kaplan EL; Blumer JL, et al. (2011). **Serum Penicillin G Levels Are Lower Than Expected in Adults within Two Weeks of Administration of 1.2 Million Units** *PLoS ONE* 6(10).

Leleu, TD; Jacobson, IG; LeardMann, CA; Smith, B; Foltz, PW; Amoroso PJ; Derr, MA; Ryan, MAK; and Smith, TC For the Millennium Cohort Study Team. (2011 OCT). **Application of latent semantic analysis for open-ended responses in a large, epidemiologic study.** *BMC Medical Research Methodology*. 11:136.

Smith, TC for the Millennium Cohort Study Team. (2011 JULY). **Linking Exposures and Health Outcomes to a Large Population-Based Longitudinal Study: The Millennium Cohort Study.** *Military Medicine*, 176(7):56-63.

Mansfield, AJ; Bender, RH; Hourani, LL; and Larson, GE. (2011 MAY). **Suicidal or Self-Harming Ideation in Military Personnel Transitioning to Civilian Life.** *Suicide and Life-Threatening Behavior*, 41:392–405.

Jankosky, CJ; Hooper, TI; Granado, NS; Scher, A; Gackstetter, GD; Boyko, EJ; Smith, TC and for the Millennium Cohort Study Team. (2011 JUNE 15) **Headache Disorders in the Millennium Cohort: Epidemiology and Relations With Combat Deployment.** *Headache*. 0017-8748.



Welcome Aboard

~ NHRC Welcomes the following ~

Medical Modeling, Simulation & Mission Support Dept

Doug Lowe, Technical Analyst
Erica Wessels, Student Intern
Samantha Ponce, Intern/Student Worker
Dr. Ross Vickers, Consultant

Warfighter Performance Dept

Rachel Markwald, Applied Physiologist
Ailish White, Research Assistant

Behavioral Sciences and Epidemiology

Sonya Norman, Senior Research Scientist
Kathleen Onofrio, Creative Communications Specialist
Dr. Marc Taylor, Research Psychologist
Ryan Cantor, Research Associate

Deployment Health Research Dept

Dr. Donald Slymen, Biostatistician
Lawrence Wang, Intern
William Lee, System & Database Administrator

HIV/AIDS Programs Dept

Michelle Linfesty, Director of Operations

Respiratory Diseases Research Dept

Michelle Ricketts, Research Assistant

Information Services

Eugene Martos, Information Technology Specialist

Institutional Review Board

Nancy Valladares, Research Analyst

Changes to Note

Jomelynn Fontecha— Last name change to Fontecha Lim
Susan Eskridge— Title change from Mrs. To Dr. (Epidemiologist)

American Indian Heritage Month celebrated

Brenda Crooks presents at Navy Region Southwest celebration

American Indian Heritage Month is observed every November. Ms. Brenda Crooks was invited by the Diversity Program Committee of the Commander Navy Region Southwest (CNRSW) to speak at the Navy Region Southwest's celebration.



Ms. Brenda Crooks
wearing Native American formal regalia

The motto was "Service, Honor, and Respect: Strengthening Our Cultures and Communities". Ms. Crooks presentation title was 'Native Americans' where she spoke eloquently about the unique and diverse American Indian Heritage in general; her personal life, and she elaborated on the contributions of the young Navajo men who transmitted secret communications on the battlefields of WWII notably known as the Navajo Code Talkers.

The event was held at the NRSW headquarters in San Diego, and was attended by over 60 members of the command's leadership and staff. Ms. Crooks has been the Executive Secretary to the Commanding Officer of NHRC for 45 years and is a member of the Navajo/Oneida tribes.



NHRC Command celebration

NHRC also celebrated this rich heritage by hosting a command diversity event. Honored guest speakers included CAPT Gregory Utz, who provided a welcoming introduction. Ms. Brenda Crooks, Ms. Claire Wolf, and Mr. Julian Granado presented information on Native American culture, health, and their unique tribes' traditions. To the delight of the participants, Ms. Crooks wore her native dress, while Ms. Wolf shared photos of her ancestors. The Command Diversity Action Officer, LCDR Marla McClellan presented a poster on Native American scientific leaders who have greatly impacted health care and contributed to research, while the Assistant Command Diversity Action Officer, Maj Nisara Granado, provided a demonstration and hands-on workshop on how to construct dream catchers.



Ms. Claire Wolf shows pictures of her family on
the Lone Pine Paiute—Shoshone Reservation

With many tribes recognized by the Bureau of Indian Affairs, and states with names that are of Native American origin, we revere the significant contributions Native Americans have made to the history and diversity of our military and nation.



SPOTLIGHT—

Mr. Vern Wing

Mr. Vern Wing joined the Naval Health Research Center Medical Modeling, Simulation & Mission Support Department in January 2010.

He is a nationally recognized analyst who was awarded the Richard H. Barchi prize and the David Rist prize by the Military Operations Research Society for demonstrated excellence in, and contribution to, the field of operations analysis.

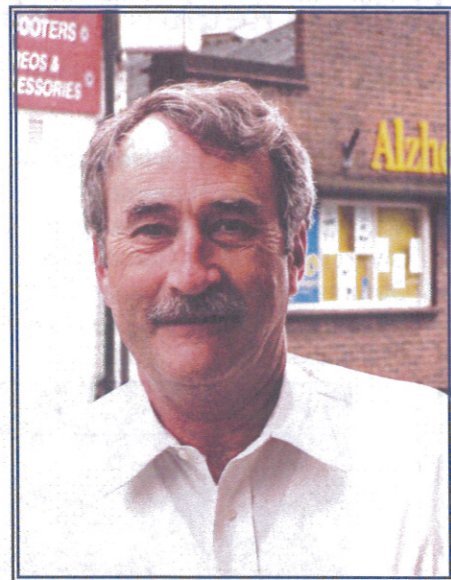
As a self described "data wonk", Mr. Wing has found a niche in the Expeditionary Medicine Modeling, Simulation, and Analysis division where he supervises the development of

models of expeditionary medical facilities in Expeditionary Medical Knowledge Warehouse (EMedKW), a web-based data management system for clinical and medical logistics scenarios, oversees analyses and studies for a variety of customers, and manages development and maintenance of Tactical Medical Logistics Planning Tool (TML+) and Enterprise, Estimating Supplies Program (EESP).

He has also been actively engaged in developing business for the department and in providing timely, relevant analyses to our customer base.

Mr. Wing served in the Navy for 28 years as a surface line officer. His Navy career took him around the world as he rose through the enlisted ranks to command the USS Copeland (FFG 25), a guided missile frigate (FFG) here in San Diego. For the past 16 years, since leaving the Navy, he has worked in program management, military operations analysis, software development, and defense acquisition roles.

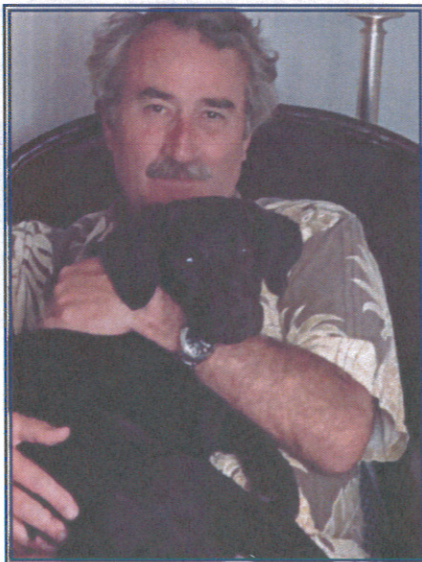
Vern is a northern Californian by birth and a



San Diegan by choice. He was born and raised in a small town near Lake Tahoe and graduated from the University of Washington and the Naval Postgraduate School.

In his off hours, Vern is an avid golfer whose enthusiasm for the sport offsets his high handicap. He can also be seen walking his black Labrador around Coronado where he lives with his wife, Darcy.

The Wing's have two children and four grandchildren. Their son, Alan, is an active duty Commander who is currently assigned to duty with NATO in Belgium. While this makes it a bit difficult to see the grandchildren, it plays into Vern's love of travel.



Vitamin D — Continued from Page 07

and calcium supplementation on bone status. The relative risk of cancer was 60% lower in those assigned to vitamin D with calcium, compared with placebo. This was statistically significant for all cancers combined. This confirmed experimentally that higher intake of vitamin D and calcium helped reduce the risk of cancer. More specifically, it was a step toward confirming an earlier hypothesis by Dr. Edward Gorham, Dr. Frank Garland, and Dr. Cedric Garland theorizing that vitamin D intake reduces the risk of breast cancer.

A pooled analysis from NHRC and UCSD found that the intake of 2,000 IU per day of vitamin D3 and moderate sun exposure could increase serum 25(OH)D to over 50 ng/ml associated with 50% lower risk of breast cancer. There are now 10 epidemiological studies indicating that lower serum concentrations of 25-hydroxyvitamin D are associated with higher risk of breast cancer. The benefit appears to be mainly from reduction in incidence of ductal and lobular adenocarcinoma.

Prevention of cardiovascular disease

Dr. E. Giovannucci of Harvard found that individuals with 25(OH)D levels ≤ 15 ng/ml had higher risk of myocardial infarction than those with

high concentrations. Intermediate levels (15–22 ng/ml) had higher risk compared with higher levels (23–30 ng/ml). Wang studied 1,739 Caucasian subjects in relation to vitamin D and cardiovascular disease. Categories of serum 25(OH)D deficiency were set at <15 ng/ml and <10 ng/ml. Subjects with serum 25(OH)D <15 ng/ml had a hazard ratio of 1.62 for cardiovascular disease incidence compared with individuals who had serum 25(OH)D levels ≥ 15 ng/ml. Data suggests that vitamin D deficiency and cardiovascular disease are closely correlated.

Reduction in risk of Parkinson's disease

Dr. P. Knekt and colleagues conducted a cohort study to determine the correlation between serum 25(OH)D levels and the risk of Parkinson's disease. Dr. Anastassios G. Pittas et al. followed 83,779 women and reported there was 33% lower risk of the disease in women whose daily intake of vitamin D was >800 IU and daily intake of calcium was $>1,200$ mg.



Further Reading:

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Giovannucci EL, Liu, Y, Hollis, BW, & Rimm, EB et al. (2008). **25-hydroxyvitamin D and risk of myocardial infarction in men: A prospective study.** *Archives of Internal Medicine*,. 2008 Jun 9;168(11),1174–1180.

Hyppönen, E, Läärä, E, Reunanen, A, Järvelin, MR, Virtanen, SM. (2001). **Intake of vitamin D and risk of type 1 diabetes: A birth-cohort study.** *Lancet*,. 2001;358(9292), 1500-1503.

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Munger, KL, Levin, LI, Hollis, BW, Howard, NS, Ascherio, A. Munger K, et al. (2006). **Serum 25-hydroxyvitamin levels and risk of multiple sclerosis.** *Journal of American Medical Association*,. 2006;296(23),2832–2838

Mohr, SB, Garland, CF, Gorham, ED, Grant, WB, & Garland, FC. et al. (2007). **Is ultraviolet B irradiance inversely associated with incidence rates of endometrial cancer: an ecological study of 107 countries.** *Preventative Medicine*,. 2007 Nov;45(5),327-331.

Highlights—Continued from Page 6

NHRC briefs on findings from a Tactical Medical Logistics Planning Tool analysis

Mr. Vern Wing provided a brief at the Expeditionary Health Service Support (EHSS) Capabilities Based Assessment (CBA) workshop on findings from a Tactical Medical Logistics Planning Tool (TML+) medical requirements analysis for the proposed Navy 10-bed Expeditionary Medical Unit. The workshop, hosted by BUMED M5B4 Fleet Futures and held at the Harbor Inn on the Sub Base in San Diego included representatives from BUMED and OPNAV-931 and discussed, among other things, Fleet and Marine Corps EHSS concerns and how they will be addressed by the ongoing CBA. SEPT 2011

First ever controlled trial of pre-deployment stress mitigation training finished

Dr. Chris Johnson, Dr. Nate Thom and Ms Ingrid Wilson finished the first ever controlled trial of a pre-deployment stress mitigation training program for 1MEF Marines at Camp Pendleton. Data was collected from 8 organic platoons comprising 24 squads and nearly 300 Marines at 3 distinct time-points. SEPT 2011

Defense Science Board briefed on brain science and Warfighter performance research

Dr. Chris Johnson presented a brief focused on the current program of brain science and warfighter performance research being conducted at NHRC and sponsored by ONR to the Defense Science Board (DSB). The DSB Task Force members present included the Honorable Judith A. Miller, former DoD general counsel and Bechtel; Gen. Michael W. Hagee, USMC (Ret), former commandant, USMC, and president and CEO – Admiral Nimitz Foundation; Mr. James R. Gosler, former director, Clandestine Information Technology Office, CIA, and Sandia; and Mr. V. Larry Lynn, former director, DARPA. AUG 2011

Mindfulness-based fitness training sessions completed.

The final session of mindfulness-based mind fitness training (MMFT) for I Marine Expeditionary Force (I MEF) Marines has been completed. A total of 142 Marines comprising 4 organic platoons, participated in 20+ hours of instruction plus practice over 8-weeks. A leadership group of 15 Marines also participated in 20+ hours of training over 8-weeks. Marines from the leadership group comprised battalion-level staff officers and senior NCOs, as well as the Deputy Commanding General of I MEF. Post-MMFT assessments were scheduled at Camp Pendleton. Infantry Immersion Trainer (IIT) for 1-4 Battalions were also scheduled. At the conclusion of the final IIT session, a total of 283 Marines will have participated in this study, which includes the assessment and evaluation of 8 organic platoons at the IIT. Neuroimaging is nearly complete, with 70 out of 80 scans successfully conducted. The remaining 10 functional magnetic resonance imaging (fMRI) sessions were scheduled for completion in Sept. This is the first ever large-sample controlled trial of a cognitive-based performance tool being delivered to warfighters during the pre-deployment cycle. AUG 2011

H1N1 Vaccine in Pregnancy Study presented to National Task Force

Dr. Ava Marie Conlin gave an H1N1 Vaccine in Pregnancy Study presentation (via teleconference) for the National Vaccine Safety Task Force. The team is developing a protocol, surveys, and forms for the Anthrax Vaccine in Pregnancy Registry. Cooperative research and development agreements (CRADA) and TOROs are also in development. AUG 2011

Highlights — Continued from Page 14

Navy-Marine Corps Combat Trauma Registry Expeditionary Medical Encounter Database participates on Blast Injury Task Force

The Assistant Commandant of the Marine Corps (ACMC) has tasked the Marine Corps to stand up a Dismounted Complex Blast Injury (DCBI) Task Force (TF) to look into anything and everything being done in the Marine Corps and Navy Medicine to address DCBI on both sides of the "Bang." CAPT Jonathan Haun is the overall TF lead. CAPT Haun has requested that NHRC's Navy-Marine Corps Combat Trauma Registry Expeditionary Medical Encounter Database (CTR EMED) participate as a TF member providing the medical and tactical analysis piece. The CTR EMED has been tracking each DCBI (tri-service) that has occurred during the past two years and develops detailed clinical and tactical profiles for each within seven days of the casualty's injury. AUG 2011

Ground Forces Casualty Forecasting System Update Project funded

The Medical Modeling, Simulation & Mission Support department received notification from Office of the Chief of Naval Operations' (OPNAV) Assessment Division (N81) that they have funded the Ground Forces Casualty Forecasting System (FORECAS) Update Project. This one-year project will provide NHRC with the opportunity to modernize FORECAS by converting it to ICD-9 patient condition codes, and will avail us the opportunity to re-examine the underlying mathematical models to determine whether they are still appropriate. The modernized tool will allow an analyst to use a standard method for deriving casualty streams across the range of military operations, and will produce Tactical Medical Logistics Planning Tool (TML+) compatible input files. AUG 2011

NHRC receives FY12 World Class Modeling Task Solution Summaries

The Medical Modeling, Simulation & Mission Support department received the FY12 World Class Modeling (WCM) Task Solution Summaries, which define the WCM analysis challenges for the fiscal year. Last year, NHRC won two awards in support of the WCM effort. This work allows us to showcase NHRC analytic skill before the Office of the Chief of Naval Operations' (OPNAV) Assessment Division (N81) customer, and provides us with the opportunity to enhance our modeling and simulation product line. This year's challenges feature an opportunity to build up the level three capabilities of TML+ by instantiating the Expeditionary Medical Facility and representations of capability modules that will allow adaptations of medical treatment facilities through plug and play capability sets. AUG 2011

NHRC's Behavioral Health Needs Assessment Survey mentioned in confirmation hearing testimony

Adm. Jonathan W. Greenert, who became the 30th U.S. Chief of Naval Operations on 23 SEP 2011, mentioned the Behavioral Health Needs Assessment Survey (BHNAS) in his confirmation hearing testimony before the Senate Armed Services Committee in Washington, DC. When asked 'what actions he would take to ensure that sufficient mental health resources are available to Navy personnel on deployment, and to their families upon return to home station', Adm. Greenert responded, "In order to understand the behavioral health needs of our Sailors serving in theatre, we deployed a Mobile Care Team to administer the Behavioral Health Needs Assessment Survey which allows real-time surveillance and intervention as needed. If confirmed, I will continue to ensure we have the proper number of mental health providers in place to address the medical, physical, psychological, and family readiness needs of our Sailors and their families."—NHRC maintains the BHNAS and has deployed with the Mobile Care Team. JULY 2011



Respiratory Disease — Continued from Page 2

Adenovirus

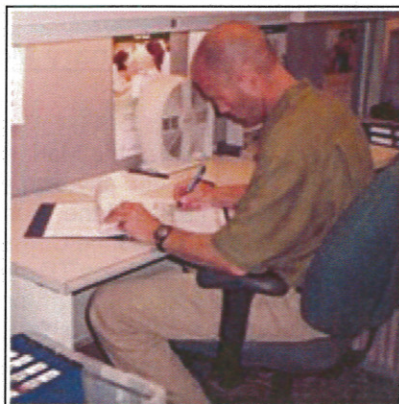
Due to a resurgence of adenovirus disease after discontinuation of the vaccine in 1999, Barr Laboratories, Inc., offered to produce the vaccine again and the FDA mandated a Phase II/III clinical trial. In 2006, NHRC in conjunction with Barr Labs and Walter Reed Army Institute of Research, began a Phase III multicenter double-blind randomized placebo-controlled study in military recruits to study the safety and efficacy of the newly manufactured oral ADV-4 and ADV-7 vaccine.

Between 2006 and 2008, DRDR enrolled 4,070 recruits from the Great Lakes Recruit Training Command and Fort Jackson. This study supported the FDA approval of a single dose of the live oral vaccine for the prevention of febrile acute respiratory disease caused by these adenovirus strains in recruits.

The vaccine has been shipped, and distribution to recruit training centers initiated in October 2011. DRDR will continue routine FRI surveillance and participate in fulfilling FDA post marketing surveillance requirements.

Japanese Encephalitis

Service members stationed in or deployed to certain regions of Southeast Asia are at risk for a rare viral infection transmitted by mosquitoes in the *Culex tritaeniorhynchus* group. The resulting disease, termed Japanese encephalitis (JE), is characterized by fever



CDR Dennis Faix reviewing subject records

and severe inflammation of the brain and can be fatal.

Since the 1970s, at-risk populations have been vaccinated. However, production of the mouse brain-derived JE vaccination (JE-VAX) was discontinued in 2006, and all remaining doses have expired.

A new Vero cell-derived vaccine (IXIARO) has been licensed as a two-dose primary series. To test whether prior JE-VAX recipients might be adequately protected against JE disease after a single "booster" dose of IXIARO, DRDR partnered with the Centers for Disease Control and Prevention Division of Vector-Borne Infectious Diseases to conduct a vaccine trial among Camp Pendleton Marines receiving IXIARO prior to deployment. Results demonstrated that adequate protection after a single dose of IXIARO was achieved. This finding will be useful in driving DoD recommendations.



Smallpox

DRDR, in conjunction with sanofi pasteur and the Military Vaccine (MILVAX) Agency, are conducting a Phase IV safety study of the newly approved ACAM2000 smallpox vaccine in deploying military personnel.

Smallpox was eradicated in nature in 1977, but heightened concerns over bioterrorism have brought smallpox and smallpox vaccination back to the forefront. The previously licensed smallpox vaccine in the United States, Dryvax (Wyeth Laboratories, Inc., New York, NY)), was highly effective, but the supply was insufficient to vaccinate the entire current US population.

Additionally, Dryvax had a questionable safety profile since it consisted of a pool of vaccinia virus strains with varying degrees of virulence, and was grown on the skin of calves, an outdated technique that poses an unnecessary risk of contamination.

The U.S. Government supported development of an improved live smallpox vaccine. This vaccine's manufacturer, Acambis, Inc. (now Sanofi Pasteur Biologics Co.), received approval for ACAM2000 to replace the Dryvax in 2007, and 200 million doses of ACAM2000 have been produced for the U.S. Strategic National Stockpile.

The FDA-required post marketing surveillance project is currently being conducted by DRDR at 6 military bases across the United States to measure the rates of clinical and subclinical vaccine-associated myopericarditis and other side effects. Enrollment is nearing half way to the target of 20,000 subjects, with completion projected in 2014.

Command Social Committee

"Fun"ctions**Summer Picnic**

Becki Grass entertained everyone

Photo Courtesy of Nelly Putnam

Tug-of-War was also a hit with the military still trying to tug their way to a win.

After all the fun and games, CAPT Utz presented the winning trophies to the following:

Horse shoes - The Ringers. Martin Lebedda & Trevor Elkins. They defended their 2010 championship title.



Have fans, will travel.

Photo Courtesy of Nelly Putnam

The NHRC Summer Picnic/Awards Ceremony was held on 28 July 2011 at Admiral Baker Park.

CAPT Greg Utz presented the following awards:

** Navy Commendation Medals to CDR Deborah White and Major Nisara Granada.

** A Special Achievement award to Dr. Edward Gorham.
(See Awards story on page 9)

The highlight of the picnic this year was the addition of the 3 x 3 Basketball Tournament. Seven teams battled for the 1st Place trophy and after 5 grueling games 'Death at the Net' - team members Brian Nelson, captain; Kevin Heltemes; Justin Hoopes came out on top.



Group shot of the basketball participants

Photo Courtesy of Nelly Putnam

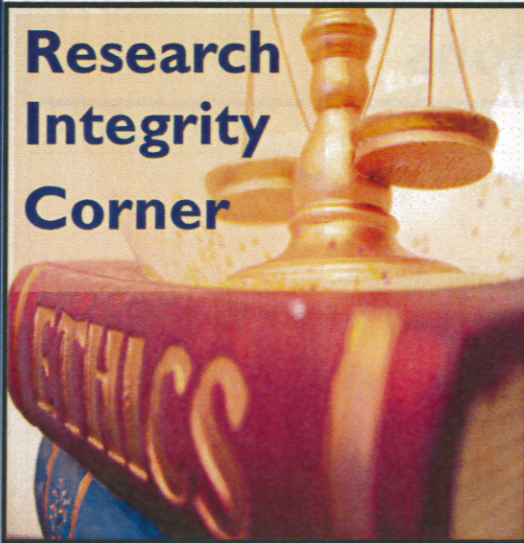
Volley Ball - CSC Fireballs.

Brian Nelson, Captain; Claro Garcia, Sonya Davis, Melissa Myers, Brenda Crooks, and Emma Casares

Tug of War - Francis DeJesus, Captain. Reuben Smith, Tom Gao, Ernest Mejia, Scott Vo, Jason Brown, Jose DeLeon, Liz Hunt and others.

With the basketball games and tug-of-war, there were many tired people at the end of the picnic, including Greg "Mac" McCurtis, the games coordinator and basketball referee. Thank you Mac!

Research Integrity Corner



"What are the main ethical principles that govern research with human subjects?"

There are three primary ethical principles that are traditionally cited when discussing ethical concerns in human subject research.

- The first ethical principle cited by the influential Belmont Report is **autonomy**, which refers to the obligation on the part of the investigator to respect each participant as a person capable of making an informed decision regarding participation in the research study. The investigator must ensure that the participant has received a full disclosure of the nature of the study, the risks, benefits and alternatives, with an extended opportunity to ask questions. The principle of autonomy finds expression in the informed consent document.
- The second ethical principle is **beneficence**, which refers to the obligation on the part of the investigator to attempt to maximize benefits for the individual participant and/or society, while minimizing risk of harm to the individual. An honest and thorough risk/benefit calculation must be performed.
- The third ethical principle invoked in research with human subjects is **justice**, which demands equitable selection of participants, i.e., avoiding participant populations that may be unfairly coerced into participating, such as prisoners and institutionalized children. The principle of justice also requires equality in distribution of benefits and burdens among the population group(s) likely to benefit from the research.

Did you know that in most cases these principles also apply to archival tissue samples? IRB's have increasingly required that explicit consent be obtained, if practical, before archived tissue can be used for research. Archiving samples for an unspecified "future use" without explicit consent undermines the autonomy of the participants. Even if participants may be willing in general to have surplus tissue used for research purposes, they should still be asked for their consent.

A more complete enumeration of these principles is available in the *Belmont Report*, written by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.

Information provided by the University of Washington
<http://depts.washington.edu/bioethx/topics/resrch.html>





CAPT Gregory Utz
Commanding Officer

Commanding Officer's Corner

New Year Brings New Acquisition Capabilities to Navy Medical R&D Enterprise

As we look forward to the New Year, we also can anticipate a wider variety of acquisition capabilities in support of our enterprise research requirements. These include contracting support, grants, and cooperative agreements administered through our contracting agency partners at Naval Medical Logistics Command (NMLC) and Army Contracting Center, Natick.

Advances in contracting support include the addition of Omnibus 3 to our Omnibus 1 and Omnibus 2 family of pre-competed multiple-performer contracts available through Natick.

Omnibus 3 will

- Provide rapid access to 21 prime performers and over 200 subcontractors, including more than fifty universities.
- Support "firm-fixed-price" task order awards or "cost-plus-fixed-fee" awards. These latter award types may be severable or non-severable.
- Allow funding of individual task orders with Program 6 R&D, Program 8 O&M or Program 8 R&D funds.

Omnibus 3 has a five-year period of performance with no ceiling limitations to individual contracting companies aside from the base-contract ceiling which is \$497M. The NHRC Scientific Support Office can assist principal investigators in preparation of their Requests for Proposals and source selection.

As of 9 December 2011, NHRC is also pleased to announce an additional Investigational Research Omnibus Contract (IROC) crafted over a two year period with NMLC. Like Omnibus 3, IROC is a pre-competed multiple-award contract, which is specifically designed to support the Clinical Investigation Programs at 28 Navy Medical Treatment Facilities, BUMED, NMRC-enterprise R&D laboratories, and NHRC for the Clinical Investigations Program (Program 8) and other clinical research support. IROC has a five-year period of performance and \$49M capacity.

Additionally, at NMLC, we have launched the Navy Expeditionary Medicine Omnibus (NEMO) Broad Agency Announcement. This BAA can support award of grants or cooperative agreements in the medical R&D 6.1-6.3 funding lines. Official approval and an announcement are expected during the next few weeks.

The establishment of this variety of acquisition capabilities will enhance our ability to obligate funds in a timely way in the coming year in support of our Navy Medical CIP and R&D enterprise.



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Mission: To conduct health and medical research, development, testing, evaluation, and surveillance to enhance deployment readiness of DOD personnel worldwide

Vision: World-class health and medical research solutions anytime, anywhere.